

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Atty Dkt. 3665-21

C# M#

SALOMON, B. et al.

Group Art Unit: 1632

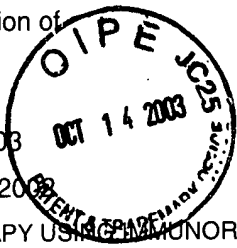
Serial No. 10/067,503

Examiner: WILSON

Filed: February 7, 2003

Date: October 14, 2003

Title: CELL THERAPY USING IMMUNOREGULATORY T-CELLS



1632

Image

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**RESPONSE**

This is a response/amendment/letter in the above-identified application and includes an attachment which is hereby incorporated by reference and the signature below serves as the signature to the attachment in the absence of any other signature thereon.

☒ **Correspondence Address Indication Form Attached.****Fees are attached as calculated below:**

Total effective claims after amendment	0	minus highest number		
previously paid for	20	(at least 20) =	0 x \$ 18.00	\$ 0.00
Independent claims after amendment	0	minus highest number		
previously paid for	3	(at least 3) =	0 x \$ 86.00	\$ 0.00
If proper multiple dependent claims now added for first time, add \$290.00 (ignore improper)				\$ 0.00
Petition is hereby made to extend the current due date so as to cover the filing date of this paper and attachment(s) (\$110.00/1 month; \$420.00/2 months; \$950.00/3 months)				\$ 0.00
Terminal disclaimer enclosed, add \$ 110.00				\$ 0.00
<input type="checkbox"/> First/second submission after Final Rejection pursuant to 37 CFR 1.129(a) (\$770.00)				\$ 0.00
<input type="checkbox"/> Please enter the previously unentered, filed				
<input type="checkbox"/> Submission attached				

**Subtotal \$ 0.00**

If "small entity," then enter half (1/2) of subtotal and subtract

-\$ 0.00

☐ Applicant claims "small entity" status. ☐ Statement filed herewith

Rule 56 Information Disclosure Statement Filing Fee (\$180.00)

\$ 0.00

Assignment Recording Fee (\$40.00)

\$ 0.00

Other: Response

0.00

**TOTAL FEE ENCLOSED \$ 0.00**

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140. A duplicate copy of this sheet is attached.

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NIXON & VANDERHYTE P.C.  
By Atty: B. J. Sadoff, Reg. No. 36,663

Signature: 



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SALOMON, B. et al.

Atty. Ref.: 3665-21

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For: CELL THERAPY USING IMMUNOREGULATORY T-CELLS

\* \* \* \* \*

October 14, 2003

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Alexandria, VA 22313-1450

Sir:

**RESPONSE**

Responsive to the Official Action dated September 11, 2003, the applicants elect, with traverse, the subject matter of the Examiner's Group I for further prosecution in the above.

Reconsideration and withdrawal of the restriction requirement, at least with regard to the Examiner's Groups I and II, are requested and consideration of the following in this regard is requested.

The applicants have elected the subject matter of the Examiner's Group I, i.e., claims related to a method of treating an immune disease using non-genetically altered T-cells that suppress a pathological immune response (claims 1-14, and 16). The Examiner has asserted that claims drawn to a method of treating an immune disease using genetically altered T-cells that suppress a pathological immune response however

are separately patentable. See, Examiner's Group II. The basis of the restriction between Groups I and II is that, according to the Examiner, "non-genetically modified cells suppress the pathological immune response... while genetically modified cells in Group II deliver proteins not produced by the T-cells that suppress the pathological immune response." See, page 2 of the Office Action dated September 11, 2003 (Paper No. "090803"). The Examiner also states at page 6 of Paper No. "090803" that restriction is proper because the subject matter of the separate Groups have acquired a separate status in the art because of their recognized divergent subject matter, as apparently supported by the Examiner's classification of the subject matter of Group I in Class 424, subclass 93.7 and the subject matter of Group II in Class 424, subclass 93.2.

Initially, the applicants note that while the subject matter of the Examiner's Group II relates to methods of treating an immune disease using genetically altered T-cells that suppress a pathological immune response, the recited treatment of the methods of both the Examiner's Groups I and II is due to an amount of immunoregulatory T-cells effective at suppressing a pathological immune response. Such T-cells effective at suppressing a pathological immune response can be further genetically modified, as recited in the Examiner's Group II. The genetic modification of the Examiner's Group II is used to increase the efficiency of immunoregulatory T-cells. See, for example, page 12, line 18 to page 13, line 6 of the specification. It is thus believed that using non-genetically altered immunoregulatory T-cells or genetically modified immunoregulatory T-cells constitutes a single invention which should be examined in the same application.

Accordingly, the Examiner's basis for the restriction requirement, at least with regard to the Examiner's Groups I and II, is submitted to not support maintaining the restriction requirement. Withdrawal of the restriction requirement, at least with regard to the Examiner's Groups I and II is requested.

As for the Examiner's assertion relating to a recognized separate status in the art for the indicated Groups of claims, the applicants note that the following 37 patents have issued wherein Class 424, subclasses 93.7 and 93.2, i.e., those indicated in the Examiner's Group I and II, were searched, as evidence of the overlapping nature of this subject matter.

*Searching 1976 to present...*

**Results of Search in 1976 to present db for:**

**CCL/"424/93.7" AND CCL/"424/93.2": 37 patents.**

*Hits 1 through 37 out of 37*

<b>PAT. NO.</b>	<b>Title</b>
1 6,613,320	<u>Defective CD4+T-cells that express active CD40-L</u>
2 6,613,319	<u>Long-term expression of erythropoietin and growth hormone by transforming muscle cells</u>
3 6,569,421	<u>Treatment of brain damage</u>
4 6,538,174	<u>Animal model for transplantation</u>
5 6,465,247	<u>Mammalian myeloid progenitor cell subsets</u>
6 6,461,865	<u>Calreticulin-deficient cells</u>
7 6,451,305	<u>Methods for stimulating T cell responses to tumor cells expressing LFA-3 and a CD28 or CTLA4 ligand</u>
8 6,403,080	<u>Methods of modulating an immune response to antigen, and cells for use in the method</u>
9 6,387,369	<u>Cardiac muscle regeneration using mesenchymal stem cells</u>
10 6,338,845	<u>Tumor killing effects of enterotoxins, superantigens, and related compounds</u>
11 6,328,969	<u>Method and compositions for stimulation of an immune response to a differentiation antigen stimulated by an altered differentiation antigen</u>
12 6,326,465	<u>Immunomodulatory polypeptides derived from the invariant chain of MHC class II</u>

- 13 6,299,873 Method for improvement of radiation therapy of malignant tumors
- 14 6,264,943 Method for transplanting cells into the brain and therapeutic uses therefor
- 15 6,251,385 Method of cancer treatment
- 16 6,225,119 Production of megakaryocytes by the use of human mesenchymal stem cells
- 17 6,221,351 Tumor killing effects of enterotoxins, superantigens, and related compounds
- 18 6,184,032 Identification of genes encoding cell surface antigens using CREF-Trans 6 cells
- 19 6,132,718 Multi-stage cascade boosting vaccine
- 20 6,068,836 Cell compositions for use in transplantation
- 21 6,048,725 Recombinant human immunodeficiency virus producing cell lines
- 22 5,912,236 Broad-spectrum tumor suppressor genes gene products and methods for tumor suppressor gene therapy
- 23 5,869,037 Adenoviral-mediated gene transfer to adipocytes
- 24 5,858,354 Repopulation of testicular Seminiferous tubules with foreign cells, corresponding resultant germ cells, and corresponding resultant animals and progeny
- 25 5,827,516 Immunomodulatory peptides
- 26 5,820,856 Modified TALL-104 cells to treat cancer
- 27 5,792,900 Compositions and methods for producing and using homogenous neuronal cell transplants
- 28 5,759,536 Use of fas ligand to suppress T-lymphocyte-mediated immune responses
- 29 5,705,150 Antigen specific plasmacytomas and antibodies derived therefrom
- 30 5,702,702 Modified cytotoxic tall cell line and compositions and methods for manufacture and use thereof as therapeutic reagents for cancer
- 31 5,690,927 Use of neuro-glial fetal cell lines for transplantation therapy
- 32 5,683,690 Modified cytotoxic tall cell line and compositions and methods for manufacture and use thereof as therapeutic reagents for cancer
- 33 5,656,481 Compositions and methods for the delivery of biologically active molecules using cells contained in biocompatible capsules
- 34 5,653,975 Compositions and methods for the delivery of biologically active molecules using cells contained in biocompatible capsules
- 35 5,487,889 Bandage for continuous application of biologicals
- 36 5,342,776 Avian hemopoietic progenitor cells
- 37 4,409,331 Preparation of substances with encapsulated cells

The applicants believe the Examiner's search of the subject matter of Group I will include a search of the subject matter of the Examiner's Group II. Moreover, the applicants assume that if the Examiner maintains the restriction requirement then art

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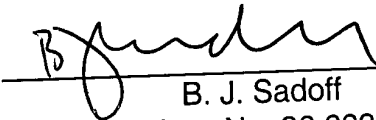
teaching the method of, for example, claim 5 of the present application, would not anticipate or make obvious the subject matter of, for example, claim 1 wherein the immunoregulatory T cells might not be genetically modified. The Examiner is requested to confirm as much in his next Action.

Reconsideration and withdrawal of the restriction requirement, at least with regard to the Examiner's Groups I and II, are requested.

An early and favorable Action on the merits of the claimed invention is requested.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

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